DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 11, 2001, from 9 a.m. to 5 p.m.

Location: National Institutes of Health, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Contact: Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, Woodmont II Bldg., 1451 Rockville Pike, Rockville, MD 20752, 419-259-6211, or John Treacy or Jayne E. Peterson, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug applications (NDA) 20–665 (capsules) and NDA 21–283 (tablets) Diovan® (valsartan), Novartis Pharmaceuticals Corp., for the treatment of patients with heart failure.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 5, 2001. Oral presentations from the public will be scheduled between approximately oc01229

9 a.m. and 10 a.m. on October 11, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 5, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 9-18-01

September 18, 2001.

Linda A. Suydan,

Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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